The Organ Procurement Organization (OPO) Committee
Report to the OPTN Board of Directors
June 21 - 22, 2010
Richmond, VA

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- OPO Performance Metrics. The Committee has worked with the MPSC and the SRTR to develop a performance metrics model that, based on donor characteristics, can predict expected organs transplanted per donor (OTPD) and compare it to the observed OTPD. A conference will be held in May to educate the OPO community about the new metrics model and its goal of performance improvement. (Item 1, Page 3)

- Multi System Organ Failure. This subcommittee is identifying ways to standardize the multi system organ failure (MSOF) portion of the eligible death definition in order to promote more consistent data reporting. (Item 3, Page 6)

- New Organ Transport Labels. The Committee has developed a new organ transport labeling system that is color coded and organ specific. This new system was developed to prevent labeling errors. (Item 6, Page 7)

- DCD Joint Work Group. The joint OAC/OPO Committee Work Group has divided into two subcommittees that will address: 1) definitions for DCD in DonorNet® and 2) DCD policy development and/or modification. (Item 8, Page 11)

- Standardizing Abbreviations in DonorNet®. The Transplant Administrators Committee (TAC) is seeking input regarding its work with standardizing abbreviations in DonorNet®. The Work Group is interested in developing a glossary of accepted terms and abbreviations and in evaluating opportunities to develop additional educational tools. (Item 16, Page 22)

- Data Coordinator Defined. The Committee has provided the MPSC with a recommended definition for the data coordinator and supports the inclusion of this definition in policy. (Item 18, Page 23)

- When Donor Information Changes after an Offer has been Made. A new Joint Work Group has been formed to discuss the issues surrounding when donor information changes following an offer in DonorNet®. (Item 19, Page 25)

This page is intentionally left blank.

The Organ Procurement Organization (OPO) Committee
Report to OPTN Board of Directors
June 21 - 22, 2010
Richmond, VA

Jeffrey P. Orlowski MS, Chair
Lori E. Brigham MBA, Vice Chair

This report reflects the work of the OPO Committee during its meetings on November 5, 2009 and April 20, 2010, in Chicago, IL and a Committee conference call on January 12, 2010. Additionally, the OPO Performance Metrics Work Group, Policy Review, Labeling, and Multi System Organ Failure Subcommittees, as well as the joint OPO/OAC DCD and the When Donor Information Changes in DonorNet℠ Work Groups have met by conference calls/Live Meeting.

1. OPO Performance Metrics. At the November 5, 2009, meeting, Mr. Alexander provided an update of the OPO Performance Metrics project. The OPO Performance Metrics joint Work Group, comprising members of the OPTN Membership and Professional Standards Committee (MPSC), OPO Committee, and Scientific Registry for Transplant Recipients (SRTR), identified a model that would assess and predict actual vs. expected organs transplanted per donor (OTPD) by DSA. The Work Group reviewed the required fields in DonorNet® and identified the medical and social criteria necessary to evaluate. Donor demographics and characteristics collected by the OPTN were utilized in the analysis.

The Work Group reviewed organ specific data and their effect on yield and determined that the model is also able to identify variations in yield by organ. There were instances when an OPO did not meet a specific standard in the aggregate; however, it was determined that it had a low organ specific yield, not overall yield. Work Group members considered that this may be a reflection of certain factors such as acceptance practices and the presence of local programs and agreed that those programs that had local transplant programs might have a greater OTPD.

It was suggested that programs with exceptional yields from specific donors could be tracked to determine the effect of some characteristics and clinical determinations regarding outcomes. This model will promote a better understanding of the risk factors involved and is adjusted for individual DSA. The original sample included all donors between July 1, 2004, and June 30, 2008, from whom at least one organ was recovered for the purpose of transplant, (N =31,906). Variation in expected yield for different donors showed that some donors had an expected yield that was very small for a specific organ. Some donors had an expected yield of nearly 2, meaning that they were expected to yield two kidneys. However, most donors were expected to yield zero intestines.

Differences in each DSA's donor case mix and the DSA's expected average yield can also be identified by the model, and is expected to vary among DSAs. There is also variation among DSAs in observed vs. expected ratio in certain organs; however, there is currently not a large variation in organs expected for kidneys and livers. Some DSAs would be expected to perform lower, and the reasons why this occurs should be identified. Committee members questioned whether there are factors such as distance or import export status that can be evaluated. As this model is evolving, some of these factors may be able to be included in the future.

The goal of this project is to identify a model that can be used by OPOs for quality improvement. It demonstrates actual performance for an OPO compared to expected performance based on its individual case mix. In order to provide this information to the OPO Community, education is needed. To provide

the data to the community, the joint Work Group agreed that, pending Board of Directors approval at the November 2009, meeting, each OPO will receive its performance data. Mr. Alexander and the SRTR will be presenting the model at the AOPO Executive Directors meeting in January 2010. The Work Group agreed that a forum comprising procurement and clinical leadership will be planned to discuss the data.

At the January 12, 2010, Committee Conference call/Live Meeting, Mr. Orlowski provided an update of the OPO Performance Metrics Educational Conference that will be held in May in Chicago at the O'Hare Hilton Hotel. At the conference, the OPO Performance metrics will be explained, and a discussion will be provided regarding how they will be applied. Each OPO will be able to send 3 staff to the conference. The Committee agreed that the conference will provide a forum for better understanding of the metrics. The SRTR will be presenting the metrics model at the AOPO Executive Directors Meeting in January.

At the March 4, 2010, Work Group conference call/Live Meeting, SRTR staff presented the model and provided a detailed explanation of the components of the model and some of the results. The original sample included all deceased donors from July 1, 2004 – June 30, 2008, who had at least one organ recovered for transplant. The cohort has since been updated to include all deceased donors from July 1, 2005 to June 30, 2009. Data will continue to be updated as they become available.

Initially, the OPO Committee identified donor characteristics based on when the donor presented to the OPO (conditions not under the control of OPO). These characteristics were used as covariates to adjust for in the model. These variables do not include such things as whether or not the organ was pumped, but does include information such as donor gender, race, and cause of death. An ordinal logistic regression was used to model the overall number of OTPD, which could range from 1 to 8 organs.

Subsequent to the aggregate model, organ specific models were created. These organ specific models complement the aggregate model and provide an opportunity to identify performance improvement needs in specific areas.

Each of the data components was reviewed for clarification. Because OPOs have different numbers of donors, each OPO's donors were calculated per 100 donors. Calculating per 100 donors allows OPOs to be compared on the same scale. It is more informative to compare the observed (O) or expected (E) rate for donors than it is to compare the OPO yield to the national average rate. The data show that if an OPO has a low observed yield, it does not mean they are performing poorly or worse than expected. Several OPOs have a low yield but are performing as expected because of the case mix of donors in that DSA. This model can be used to compare OPOs to each other. The data spreadsheet was reviewed in detail with each data element explained. A summary is found in Table 1 below.

Table 1. Description of Each Column in the Data Table for the OPO Metrics Model.

Column	***What the data mean***
A	Total number of donors from whom at least one organ was recovered for transplant.
B	Actual number of organs transplanted from those donors
C	The number of organs expected to be transplanted from those donors.
D	Observed yield (O) per 100 donors
E	Expected yield (E) per 100 donors
F	Ratio = observed yield divided by expected yield**
G	The *p* value that indicates whether the observed yield to expected yield is statistically significantly different than 1. (This value helps to identify if OPOs are performing higher or lower than expected; however it is partially dependent on sample size.)

**In Column F:

- O to E ratio = 1, the OPO has as many OTPD as expected or, other words, they were performing as expected. For every 100 organs, there were 100 organs transplanted
- O to E ratio is <1, the OPO has less OTPD than expected (For every 100 organs expected, fewer were transplanted)
- O to E ratio is >1, the OPO has more OPTD than expected. (For every 100 organs expected, more were transplanted)

Each organ has an equal value (i.e. Kidney and liver are counted the same). When identifying opportunities for improvement, thresholds will need to be developed. Statistical significance is always a criterion for ensuring that the data are not a result of random chance.

The conclusions included:

- The yield models are highly predictive
- Can be used to adjust for differences in the case mix of donors in DSAs
- Observed rate should be compared to expected rate rather than to the national average
- Signaling tools to consider include whether the O to E ratio is less than a meaningful threshold that clinical significance and statistical significance ensures that the difference from 1 is not due to random chance

At the April 20, 2010, Committee meeting, the chair provided an update and the SRTR staff presented a brief explanation of the current status of the model. The question was posed as to whether or not the model accounts for regional differences. The donor variables are the main focus, and the model assesses individual donors within a DSA. Mr. Orlowski explained that currently, an OPO can review its own data on the SRTR secure website; however, the Executive Committee approved the release of DSA identified data so that each DSA will have the ability to compare its data with that of other DSAs. One feature of the model that might be helpful to OPOs is the "expected" organs transplanted per donor that can be identified when looking at specific donor characteristics.

The Work Group will continue to identify potential uses for the data and some form of "flagging methodology. Questions were posed as to

- whether or not there should be one flagging criteria for the aggregate model and one for each of the organ specific models
- whether or not the same criteria should be used for the conversion rate model; and
- what action will be taken when an OPO is flagged

It was suggested that the data be studied by region. The SRTR also suggested that the data for individual OPOs be compared with the data of the OPO's peers. An educational conference is planned for May 27, 2010. Three individuals from each OPO may attend. The SRTR will present the model, and there will be a discussion regarding the purpose of the metrics. All OPOs are encouraged to send their key leadership staff.

2. Data Review. At the April 20, 2010, meeting, John D. Rosendale, Biostatistician and Senior Performance Analyst, provided a review of all donor data through December 2009. When assessing all donors, there was a slight increase in the number of donors in 2009 from 2008. There were 8,022 in 2009 compared to 7,990 in 2008. The number of organs transplanted increased 1.3% and OTPD went from 2.99 to 3.02. There was a decrease in SCD donors by .8%. ECD donors increased slightly by .2% (3 donors) but the OTPD increased by 2.0%. DCD saw the largest increase with an increase of 8.5%.

3. MSOF Subcommittee. At the April 20, 2010, meeting, Mr. Orlowski provided a summary of the Multi-System Organ Failure (MSOF) subcommittee's work. This group is identifying ways to standardize the MSOF portion of the imminent and eligible death definition in order to promote more consistent data reporting. The subcommittee has developed some criteria for individual potential donors that would exclude them from being reported as imminent or eligible deaths although they may still be recovered donors:

- the brain dead patient that does not have a suitable transplantable organ however, they do not meet the definition of MSOF as defined by the Society of Critical Care Medicine's definition; and
- the brain dead consented donor that does not have a recipient

The subcommittee members agreed that MSOF is only a part of the eligible death definition and, as such, they should consider the entire definition. They will expand their name to reflect that change as the Imminent and Eligible (I & E) Definition Review Subcommittee. The goal of this group is to have more accurate data reporting. The subcommittee has suggested that a more consistent way to rule out organs that are not really in failure would be to identify specific conditions (i.e. CABG) that would render the organ as non-transplantable.

Rich Pietroski MS, CPTC, OPO Committee member, will assume the chairmanship of this subcommittee. The current definition of MSOF might be retained as:

- an etiology of overwhelming sepsis as a rule out that cannot be corrected
- uncorrected circulatory collapse (yet to be defined); and
- acute or chronic medical histories that rule out each of the organs

These areas will be the focus of the subcommittee's work as they continue to look at the definition in order to refine the data collection.

4. Imminent and Eligible (I & E) Neurological Death Data Collection Project. Mr. Rosendale provided a summary of the I & E death data collected from January 2008, to December 2009. These data are patient level data. Conversion rates (donors that meet criteria divided by eligible deaths) by characteristics were reviewed:

- Age – the highest conversion rate can be found in the 18-29 year old group at 76.3% and the lowest rate is found in the 60-70 year olds at 60.2%
- Ethnicity – the white conversion rate is highest at 76.3% and non white is about 57%
- Cause of death – patients with head trauma were identified as having the highest conversion rate at 74.6%
- Mechanism of death – patients with a gunshot wound were identified as having the largest conversion rate at 77.3% and blunt injury at 73.8%
- There is no difference between male and female conversion rate
- If an OPOs timely referral definition is met, the conversion rate was found to be about 70%; if not, 56.7%
- If an OPOs definition of effective request is met, the conversion rate was found to be 75.4%; if not it was 46.2%

There continue to be inconsistencies in the data reported (i.e. there is currently an OPO that reports no eligible deaths for every 10 imminent deaths). Since these data have been collected there has been some contact with those OPOs that were reporting no, low or exceptionally high rates to try to discover why those OPOs had such a different reporting results. It was determined that some OPOs were using their own definitions and not the definition as found in policy. One OPO had an exceptionally high number

due a data point that influenced its total and has since corrected the problem. The Committee also considered that the change of staff at OPOs can affect the reporting.

Members agreed that there needs to be some consideration regarding the differences across OPOs in the declaration of death. For example, in those states that require 2 brain death exams, if there is no possibility of gaining consent, then there may not be an incentive to have a second brain death exam. In this scenario, this patient would not be reported as eligible. However, in states having a requirement for only one brain death exam, these patients would be reported as eligible. Additionally, even if a state only requires one brain death exam, individual hospitals within that state may require two exams.

The original goal of this project was to identify areas of opportunity and growth potential. The data were never intended to be used as a combination measure, but to be used for an improvement measure. The work group may consider changing the definition (e.g. absence of respiratory drive and 3 absent brain stem reflexes) to make the interpretation of data more consistent.

5. OMB Project Update. At the April 20, 2010, meeting, Mr. Rosendale provided an update of the OMB project. The OMB Public comment time period has closed and the Committee commented on all of the responses to the proposed changes to the DDR.

Motion: That the OMB project move forward with the proposed changes to the DDR form.

The motion was approved by a vote of 13-0-0.

6. Organ Transport Label System. During the November 5, 2009, Committee meeting, Lori Markham MS, CCRN, CPTC, Chair of the Organ Transport Label Subcommittee, presented proposed changes to the organ transport labeling system, and the Committee considered several options. OPTN policy states that OPOs are required to use the standardized external shipping label distributed by the OPTN contractor; however, current policy does not require OPOs to use a standardized internal label distributed by the OPTN contractor. Currently, each individual OPO develops its own internal label, and these labels vary from OPO to OPO. As a result, internal labeling is not consistent throughout the United States. Additionally, OPTN policy requires that specific information appear on the internal label. The Committee agreed that this lack of consistency created by non-standardized labels increased the probability of errors.

The Membership and Professional Standards Committee (MPSC) reviewed labeling and packaging errors that occurred following the implementation of a new labeling system in January 2008 and asked the OPO Committee to address the issue. The Department of Evaluation and Quality (DEQ) provided a report of past labeling errors, and they are summarized in Table 2.

Table 2. Report of Labeling Errors that Occurred from March 09 – August 09.

Organ	Issue
Kidney/Liver	Incorrect UNOS ID # was put on organ labels.
Kidney	Self reported that they sent blood with the wrong UNOS ID #.
Liver	Self reported that it used a shipping box that did not meet the requirements of OPTN Policy 5.5.1 – shipped a liver in a box that was not wax coated.
Iliac Vessels	Arteries from liver and pancreas were packaged together and veins from liver and pancreas were packaged together.

Kidney	Packaged donor record and documentation outside of the box in a clear Ziploc bag
Kidney	Right and left kidneys sent to wrong transplant centers (R ↔ L)
Kidney	Tube of blood only contained donor name, no other identifiers. (Lack of required information)
Liver Segments	Left segment of liver was labeled right. (L ↔ R)
Heart	Spleen and lymph nodes were mislabeled.
Heart	Blood sent with outer box labeled but not the individual tubes of blood. (No label)
Kidney	Packaged right kidney in the left kidney jar and vice versa (R ↔ L)
Kidney	Lymph nodes were not in the box containing kidney or pancreas, the label outside the box indicated that lymph nodes were included.
Kidney	Right and left kidneys sent to the wrong transplant center (R ↔ L)

Nine of the 13 reported errors (highlighted) resulted from an organ that was mislabeled as something other than what it was (i.e. right vs. left kidney), missing required information, or not labeled at all. The other 4 errors resulted from incorrect information on the label or incorrect packaging. Based on the OPO community's input, the Committee concluded that the current labeling system was cumbersome and confusing. In response, the Committee developed a new organ-specific, color-coded system. Under the new system, a standardized internal label is color coded to match its corresponding color coded external label and each organ-specific label has its own unique color. These safeguards are being recommended to eliminate the possibility of placing a right kidney in a left kidney box as it would be very apparent that the color of the internal label does not match the external label. Additionally, the Committee developed a standard internal vessel label. All labels contain the information required by policy. When there is more than one organ packaged in a shipping container, each label for that specific organ will be layered on the box. The vessel label is the same size as the internal label and is white as opposed to a specific color.

In order to evaluate the effectiveness of the new labeling system, a pilot study involving five OPOs was conducted from January 11, 2010, to March 11, 2010. The OPOs varied in size and represented different geographic regions. The pilot sites used the new labeling system (external and internal labels for organs and internal labels for vessels) on all of their donors during the test period. They found the labels to be easy to use and extremely effective in eliminating errors. Based on their feedback, the Committee agreed that this new labeling system should be used as the standard for all OPOs and transplant centers. The pilot sites included:

- California Transplant Donor Network - California
- Midwest Transplant Network - Kansas
- Finger Lakes Donor Recovery Network - New York
- Gift of Life – Pennsylvania
- Washington Regional Transplant Consortium – Washington DC

Currently there is no standardized form available to verify packaging and labeling. Each OPO establishes an internal process and develops its individual form. The subcommittee sought input from the DEQ and MPSC regarding errors that occur and it was indicted that verification was an issue that caused errors. As a result, the subcommittee developed a form that takes into consideration all elements that are required by policy. It was determined that the form cannot be required as some OPOs have electronic systems. It was suggested that it be provided to OPOs as a helpful tool that they can elect to use.

The Committee also considered an error that occurred when a surgeon misidentified the kidneys and questioned whether it should be mandatory that the surgeon sign the verification form. It was determined that the surgeon can be the second signature that is required. If an OPO chooses to use the suggested verification form, it can be kept in the donor record and would provide all required information. The form includes a verification of the external and internal label, packaging that contains source documents for ABO, serology results, medical social history, donor record with authorization, and death pronouncements. The single page document has space for four sets of signatures. The pilot sites will also test the effectiveness and ease of use of the verification form.

The Committee was also informed of a recent event when a transplant center repackaged an organ and allowed the OPO to reallocate it without informing the OPO that the organ had been repackaged. The OPO Committee agreed that this practice poses a threat to patient safety. To avoid contamination, an organ is packaged in a sterile environment and handled with particular care. Opening an organ package presents significant risk for contamination. As such, transplant centers should inform the OPO if an organ package has been opened, if any procedures are performed, including an examination of the organ, and if the organ was repackaged.

It would be important to include the "version" date on the verification form. Mr. Orlowski will provide a letter to all OPO Executive Directors notifying them that there is a pilot study for two months. Ms. Markham will post the same information about the pilot on the AOPO Procurement Directors and Quality Council portal. UNOS staff will also send the notification to OPOs, Transplant Centers, Organ Specific and Transplant Administrators Committees, and HLA labs. Following comments from the pilot study, the Committee will consider making the internal labels mandatory.

Motion: That the Committee has reviewed the new label system, endorses the new system for pilot testing, and will review the data following the two month pilot study to determine if the label changes should be finalized.

The motion was approved by a vote of 13-0-1.

At the January 12, 2010, conference call, Ms. Markham provided an update on the work of the label subcommittee. Presently, most of the labels have been printed and distributed, and the five pilot sites are ready to begin testing their effectiveness in decreasing errors and increasing ease of use. A problem arose when it was brought to the Chair's attention that the biohazard label must, according to the Department of Transportation requirements, be a black symbol placed on an orange or orange/red background. As such, the pilot will be briefly delayed while stickers will be placed over the current symbols (which are black on a white background) in order to bring the users into compliance. The stickers and vessel labels will be sent to the pilot sites, and they can begin the study by January 11, 2010. The subcommittee will have a conference call on or around February 11, 2010, to identify any issues that the sites might have identified. Additionally the sites will complete an evaluation form.

Lori Brigham MBA, Vice-chair, proposed changes to Policy 5.0 that would require that the internal label be standardized and provided by the OPTN contractor. The Committee also agreed that when a transplant center or OPO repackages an organ, it should notify the recovering OPO of the repackaging and of any other actions that occurred such as touching the organ, anastamosis of the organ, implanting, etc. It was suggested that since this does not occur frequently, it might be highlighted in policy.

To ensure consistency, the term "distributed" by the OPTN contractor was consistently applied to replace the term "provided" by the OPTN contractor throughout the policy. One sentence was also added that explained the availability of the verification form for packaging and labeling. This form is not required.

It might be more acceptable and less prescriptive to include a sentence that OPOs must have a process in place to document the verification of packaging and labeling.

Additionally, the DTAC, while reviewing Policies 2.0 and 4.0, determined that the labeling and packaging documentation requirements should be placed in policy 5.0 as opposed to policy 2.0.

Motion: That the proposed changes be accepted and that they should be distributed for public comment. The changes:

1. Require Transplant Centers to notify the recovering OPO when they repackage an organ
2. Require the use of the standardized internal label provided by the OPTN Contractor for organ and vessel transport and for vessel storage
3. Clarify internal labeling requirements
4. Move the list of required documentation from Policy 2.5.6.1 to 5.5.1
5. Clarify documentation and internal labeling requirements for vessel storage

The motion was approved by a vote of 15-0-0.

At the April 20, 2010, meeting, the Committee reviewed the recommended changes to the labeling system based on the data collected from the pilot study. Several fields were moved to place all donor information together. The subcommittee recommended the development of labels for enbloc kidney and enbloc lungs using both of the colors used by the colors. For multiviceral or other combination of organs packaged together, the labels will be stacked. An education module in PowerPoint is being created and will be provided to everyone. It is anticipated that there will be several Live Meetings.

In the pilot study, one DSA suggested that we have a blank white label for vessels and for any organs going for research. This resulted from a transplant center that received an organ for transplant that was meant actually meant to be used for research. It was suggested that most of the time the organ is transported for transplant and not for research. The Committee did not agree that a "research" label should be developed. The Committee agreed that there should be no blank label for vessels developed by the OPTN contractor and that OPOs should create their own label or use a standard label and write vessels on it.

On each label, information in the check box was organ specific. The subcommittee asked the Committee if "vessels" should remain on the kidney label, or should it be written in under "other." The Committee agreed that vessels should remain on the kidney label. After reviewing the labeling system, the Committee made the following motion:

Motion: That the Committee authorizes the subcommittee to make any further changes in order to keep the project moving forward and that the labeling system be approved with the above proposed changes.

The motion was approved by a vote of 13-0-0.

It was estimated that the labeling system will be ready for implementation by mid-summer; however, the proposal to require the internal label provided by the OPTN contractor will be presented to the Board of Directors in November 2010. The Committee agreed that the labeling system should be implemented as soon as possible with the clear statement that the internal label is currently not required. If approved in November 2010, they would receive notification about the requirement to use the internal label. The Committee made the following motion:

Motion: That the labels should be implemented as soon as possible and prior to the approval of the requirement to use the internal label.

The motion was approved with a vote of 13-0-0.

Additionally, the pilot sites agreed that the donor documentation/verification form was helpful and recommended providing it to the community as a resource.

7. Acceptance Listing and Acceptance Practice Report (Tiered Acceptance). The Chair provided an update of the work of the Tiered Acceptance Work Group. The Work Group is working closely with Ken Andreoni, MD, chair of the Kidney Transplantation Committee as they move toward a new kidney allocation model. Instead of developing a system for all organs, the Work Group will add several renal allocation related questions to the recipient listing process to better screen kidney donors against kidney recipients (e.g. Donor risk index, kidney from 5 hours vs. 1 hour away). There are centers that never accept organs for recipients who have specific acceptance criteria listed. The questions will help to better list their patients for kidneys that are being imported. Expedited placement also continues to be considered.

The Work Group is also developing a 3-prong education plan regarding acceptance practice that will consist of:

- General newsletter article with the statement of the problem
- Letter with individual center's acceptance practice
- Follow up with Live Meeting or personal visit targeting each program regarding their listing actions

8. DCD Joint Work Group. The joint OAC/OPO Committee Work Group has divided into two subcommittees that will address definitions for DCD in DonorNet®, and DCD policy development and/or modification.

At the April 19, 2010, meeting, the subcommittee reviewed the proposed changes to the definitions and made the following recommendations to the Committee at the April 20, 2010, meeting.

- "Withdrawal of support" was changed to "withdrawal of life sustaining treatments" and defined as the actual point at which the patient's attending physician or designee begins the process of removing life sustaining treatments (this is not when the order is written)
- "Cannulation" is the time of initiation of cold preservation in situ. Although awkward, the term cannot be removed from the form presently
- Attachment III Appendix B of the Bylaws – Model Elements is being rewritten and will be sent to the Committee for further comment
- Definition of controlled DCD –Maastracht III should be used - "awaiting cardiac arrest, patient in intensive care unit with non-viable injuries, with a plan for removal of life sustaining treatment"
- Agonal phase – The agonal phase is defined for the adult as the systolic blood pressure first reaches and is sustained for a minimum of 5 minutes for less than 80 mm/Hg or an O_2 Sat of less than 80%. The subcommittee will seek input for the pediatric patient with criteria based on age and size. There was discussion of mean arterial pressure (MAP) being used as a standard; however, the group decided that MAP is not used for the pediatric patient
- Total urine output during the recovery phase – The subcommittee agreed that it is important to measure output even though the donor is not in the OR. It will be measured when life sustaining treatments are withdrawn until perfusion in situ. Once the systolic pressure is under 80 mm/Hg

or the O_2 is under 80% there is no more urine output. Once life sustaining measures are withdrawn, OPOs do not routinely measure urine output
- Cardiac Death is the legal declaration determined by the patient's physician or designee in accordance with the hospital's declaration of death policy
- Core Cooling is the initiation of cold perfusion in situ
- Warm Ischemia Time can be calculated using serial data beginning with the agonal phase and ending with core cooling
- Date and Time Organ Recovered is the time when the organ is placed in the basin

Motion: That the suggested changes be approved and provided to the Joint Work Group for consideration.

The Committee approved the suggested changes with a vote of 14-0-0.

9. Thoracic Organ Transplantation Committee Proposal to require HLA typing**.** Maryl Johnson MD, Chair of the Thoracic Organ Transplantation Committee (Thoracic Committee), sought input from the Committee regarding a proposal that would require that the HLA be entered into DonorNet® for all thoracic organs in order to evaluate a virtual crossmatch. It was the general consensus that HLA testing takes a longer time to complete than it does to complete a cross match which may delay organ recovery. Committee members commented that they would wait if the recipient is sensitized and the center needs the HLA results; however, it is currently not required.

It would be impossible for centers to send blood for their sensitized recipients to every center in a large geographic area. The question was posed as to how to best serve this type of patient. The concern of the Committee is that most recipients are not sensitized and if HLA is required pre allocation, in many cases it will not be valuable information. Although not required for allocation, if the center needs it, the OPO will not allocate the heart beyond them until the HLA is complete. In the current system, a required preliminary cross match question appears in DonorNet® and the recipient would not appear on the cross match.

In a multi-organ donor, OPOs frequently recover organs before tissue typing is completed, particularly for unstable donors. It was suggested that a survey be done of OPOs and HLA labs to determine what issues may be obstacles. Members agree that this is a patient safety issue. Members will review the survey and provide feedback to the Thoracic Committee.

If HLA is entered in the computer and the heart list is run, then patients who have unacceptable antigens on the heart list would be screened off. Also, the Committee questioned whether or not, if crossmatches are required, the heart programs would be willing to mobilize their backups. There are some programs that may have issues with this proposal and, as such, the Committee agrees that a survey of OPOs and labs is absolutely necessary.

The Committee is supportive of:
- the general concept of trying to provide this information as a way to expand the donor pool for patients who are sensitized
- completing a survey to understand the issues in the community; and
- working jointly with the Thoracic Committee so we have a workable policy recommendation

The Committee's primary opposition is to an absolute mandate that HLA be completed prior to any allocation. This opposition exists due to the logistical issues involved. The Committee is proposing several considerations for the Thoracic Committee:

- will the center be willing to accept this
- if there is a patient, backups must be lined up and the recipient center would mobilize their backup. The Committee agreed that this is necessary so organs are not wasted

It was determined that, at this time, the programming exists for screening recipients off the list if unacceptable antigens are listed for all organs. Many times the thoracic organ offers are made before HLA results are entered. Therefore, communication would have to occur after a center gives a "provisional yes."

Motion: That the Committee supports sending out the survey and will provide feedback regarding its contents by April 23, 2010.

The motion passed with a vote of 14-0-0.

10. Public Comment. At the January 12, 2010, conference call/Live Meeting, the Committee discussed the proposal to improve the variance appeal process. Members agreed that the process for appeal was well thought out and provides the members with appropriate recourse.

Motion: To approve the proposed policy as written. The Committee approved the proposed changes with a vote of 14-0-0.

At the April 20, 2010, meeting, the Committee reviewed the public comment proposals. Their comments follow:

1. **Proposed Ohio Alternative Local Unit (ALU) Liver and Intestinal Organ Transplantation Committee (Liver and Intestinal Organ Transplantation Committee)**

   The Committee was aware that Ohio had an ALU for years that allowed them to share livers to patients within Ohio with critical need as if they were one OPO. The Committee was concerned that one of the OPOs in the state was missing from the list of those participating OPOs and commented that this is not a patient-driven system. The UNOS Board recently said that it is not consistent with the Final Rule and removed the ALU. As a result, Ohio has developed this less complicated ALU. The Committee agreed that it is inconsistent with the Final Rule as one large service area is not part of the sharing agreement.

   The Committee did not support the ALU with a vote of 0-14-10.

2. **Proposed One Legacy Variance for Segmental Liver Transplantation (Liver and Intestinal Organ Transplantation Committee)**

   This variance would permit the institution performing the right and left lobe split livers to transplant one lobe into the institution's index patient and the other lobe into any other medically suitable patient listed at the institution. The variance is intended to increase the donor pool by providing an incentive to the institution receiving a liver offer to split a good-quality organ and transplant it in two recipients (an adult and a child) rather than transplanting the entire organ in one recipient.

The Committee agrees that this approach tries to incentivize centers to use segmental livers and increase the number of liver transplants. The Committee also commented that if the center can keep the liver, there is definitely incentive to split it, and more organs will be transplanted. It also sets a precedent that could be potentially used across the nation. UNOS staff will review the data to see if there has been a decline in the number of split livers. One member suggested that this makes sense from an OPO perspective, but is not sure that this is the way to solve the problem. Some centers can take the liver back to their center and split it. However, it is less likely to be accepted by the host OPO's transplant center and this disadvantages the patients on their list. If there is a pediatric patient on the top of the list in one city, and a center accepts it, if the surgeon does not split the liver at the donor hospital, they can take it back to their center and allocate it there. Whoever recovers the liver can choose where to split it. The Committee would like to see data regarding how often livers are split at one center and transplanted at another.

Motion: That the Committee approve the proposed ALU with the caveat that the data be shared in two years.

The motion was approved by a vote of 12-0-2.

3. **Proposed Region 2 Variance for Segmental Liver Transplantation (Liver and Intestinal Organ Transplantation Committee)**

This variance would allow a transplant center in Region 2 that accepts a liver for a candidate suitable for a segmental transplantation to transplant the right lobe into the institution's index patient and the left segment into any other medically suitable patient listed at that institution or an affiliated pediatric institution. This variance is intended to increase the number of transplants, allowing a single liver to be divided into two segments for transplantation, and thus removing two patients from the waiting list instead of one.

Motion: That the ALU be approved with the caveat that the data be shared in two years.

The proposed variance was approved by a vote of 11-0-3.

4. **Proposal to Develop an Efficient, Uniform National Pancreas Allocation System: Affected Policies: Policy 3.8 (Pancreas Allocation Policy), Policy 3.5 (Kidney Allocation Policy), Policy 3.2 (Waiting List), Policy 3.3 (Acceptance Criteria), Policy 3.4 (Organ Procurement, Distribution And Alternative Systems For Organ Distribution Or Allocation), and Policy 3.9 (Allocation Systems for Organs not Specifically Addressed) (Pancreas Transplantation Committee)**

Meg Rogers provided a summary of the proposed allocation schema. The purpose of this proposal is to improve the national pancreas allocation system. It was noted that 66% of pancreas transplants are SPKs. SPK candidates tend to be younger as 77% are less than 50 years old compared to 44% of kidney-alone candidates. There are currently no qualifying criteria for SPK based on presence of diabetes.

In general, SPKs follow other multi-organ transplants, zero mismatch kidneys, and payback kidneys. Pancreas allocation policy allows OPOs to choose what type of pancreas transplant

to offer- they can offer organs from the pancreas match run, the kidney-pancreas match run, or the kidney match run. As a result, there is variability across the country.

Some DSAs require the pancreas to follow the kidney. Some DSAs allow the kidney to follow the pancreas. Some have separate SPK and PA lists while others have a combined list (SPK and PA).

The key components of the proposal are that:

- Kidney follows pancreas allocation, locally
- Pancreata are allocated to recipients on a combined PA and SPK waiting list
- Consistent SPK qualifying criteria (to accrue SPK waiting time) defining uremia and diabetes for kidney and pancreas transplantation, respectively
  - Kidney: on chronic maintenance dialysis or GFR or CrCl ≤ 20 mL/min
  - Pancreas: On insulin and C-peptide ≤ 2 ng/mL OR On insulin and C-peptide > 2 ng/mL AND BMI ≤ 30 kg/m^2
- Pancreas allocation disentangled from kidney allocation

The Committee agreed that this proposed policy change maximizes the gift for families and would result in a uniform pancreas allocation system across the country. This policy change provides OPOs with a more consistent way to allocate the pancreas.

One member opined that this system disadvantages the kidney patients on the list as patients on the kidney list have a much longer wait than KP patients. If a candidate opts out of a KP due to the disadvantages of the KP, the member felt it was unethical to have to tell the patient that they will wait 6 years as opposed to a year and a half.

Motion: That the Committee support the proposed policy change with data being collected at least every six months.

The Committee supported the proposal with a vote of 11-1-0.

One member suggested that this proposal provides an opportunity for a center to accept both the kidney and pancreas then take the kidney and return the pancreas to the OPO. This would be one way to "game" the system. The Committee recommends that if the OPO offers a KP and the center accepts with plans to only use the kidney, they must return the kidney with the pancreas.

Motion: That the Pancreas Committee considers that if a center accepts a kidney/pancreas and uses the kidney only, that they should be reported to the MPSC. That the Pancreas Committee collects and analyzes how frequently the KP was accepted, the kidney transplanted for that allocated patient, and the pancreas was not used. This should be considered a reportable event and OPOs should be mandated to report this event to UNOS when this happens.

The motion was approved by a vote of 9-0-4.

5. **Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events: Affected/Proposed Policies: Policies 2.0 (Minimum**

Procurement Standards for An Organ Procurement Organization), 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Diseases or Medical Conditions, Including Malignancies, of Donor Origin), and 5.5 (Documentation Accompanying the Organ or Vessel) (Ad Hoc Disease Transmission Advisory Committee)

The proposed modifications are meant to clarify and/or improve current OPO and transplant center requirements for screening for, communicating and reporting all potential or confirmed donor-related disease and malignancy transmission events. This is a significant policy rewrite for Policy 2.0 dealing with OPO procurement requirements and 4.0 dealing with disease transmission.

The Committee voiced concerns about requiring prospective testing for toxoplasmosis for heart recipients and questioned what type of timeline is necessary for its completion. They agreed that prospectively doing histoplasmosis testing on every donor is an unreasonable burden. The Committee felt that an alternative would be send a vial of blood with the heart for the transplant center to test. It was suggested that the testing should be completed with the other tests and should not have to be completed at the time of offer. The Committee questioned whether or not the vial of blood could be sent with the heart surgeon. The DTAC recommended that the OPO complete all testing. If testing is not completed until after the recovery and the heart is transplanted quickly due to the short timeframe for transplantation, the Committee considered these two recommendations unclear and confusing.

It was clarified that OPOs would be required to provide qualified samples. Not all OPOs have the staff that can do the calculation. Members questioned whether the OPO will have to get informed consent from the recipients if the sample is not qualified for HIV, HBC or HCV. They determined that the transplant center would have to secure the informed consent and the OPO would be responsible for communicating to the transplant center that they do not have a qualified sample. The DTAC might also consider a requirement to standardize a way to document that the sample was qualified.

The proposed changes very clearly state that diagnostic testing for HIV is no longer allowed and it is clarified that screening testing is required. However, it was suggested that there still may be some OPOs that do diagnostic testing for HIV. Members agreed that this change will dramatically affect some OPOs in the country. NAT testing is permitted but not required, but OPOs must still do serological testing because it is possible to have a NAT negative result and serology positive result.

The Committee discussed policy 4.0 regarding disclosure. Specifically there are some tests that the OPO gets results fairly quickly that they can disclose within 24 hours. However, some tests that appear in an autopsy may not be returned to the OPO for 6 months, such as a result showing cancer. The Committee did not feel that 24 hours to notify the center was reasonable for an issue has taken 6 months to surface. There should be greater specificity in the policy as to what is needed to be reported within the short timeframe.

Policy 4.1.2 makes the statement that any infectious disease should be reported to health care personnel who may be affected or exposed to a particular patient. This policy would be difficult to enforce and the DTAC should proceed cautiously as statewide laws are very particular as to what information can be shared. There should be a reference to applicable

state law and the guidance should be that positive serological testing for HIV, Hep B & C should be reported by state law.

Additionally, the Patient Safety System will be burdened by the requirement that every positive culture that is returned (I.E. blood, sputum) must be reported to the system for every organ that has been allocated. This language needs to be very carefully clarified because the point of the safety system is not to report every positive culture, but to report disease transmission issues. OPOs do get a large number of positive cultures that are able to be cleared up prior to organ recovery. Language should have a clear list regarding when patient safety system should be reported.

Policy 2.2.6, states that the host OPO is responsible for making historic and laboratory assessments to identify malignant and infectious conditions that may adversely affect potential organ recipient and share the information with the transplant programs. The Committee questioned whether or not the OPO is responsible for assessing for potential malignancy. It is not possible to test for every disease.

There is a requirement that a Patient Safety contact from an OPO be available 24/7. The language should read patient safety contact "or designee" should be included in policy to be available for on call responsibility.

Policy 2.5.3, flush solutions should be documented with their lot numbers. A number of OPOs do include the lot numbers, but it is not a standard procedure and many OPOs do not include this information. This recommendation was made due to the possible need to follow up if a solution is found to be contaminated.

The Committee is encouraged to send additional feedback. The Committee chose not to take formal action at this time to provide the Committee with additional time to review the proposed changes again. They will address it again on a conference call.

6. **Proposal to Update HLA Equivalences Tables Affected/Proposed Policy: UNOS Policy 3 Appendix A (Histocompatibility Committee)**

   The purpose of this proposal is to update the tables in Appendix 3A to reflect changes in HLA typing practice and to improve the utility of the unacceptable antigens.

   The Committee chose not to comment as it does not have OPO implications.

7. **Proposal to Require that Deceased Donor HLA Typing be Performed by DNA Methods and Identify Additional Antigens for Kidney, Kidney-pancreas, Pancreas, and Pancreas Islet Offers Affected/Proposed Policy: UNOS Bylaws Appendix B Attachment IIA - Standards for Histocompatibility Testing D HLA Typing D1.000 Essential Information for Kidney Offers 3.8.2.2 Essential Information for Pancreas Offers (Histocompatibility Committee)**

   This proposal would require that OPOs and their associated laboratories perform HLA typing of deceased donors by DNA methods and identify the HLA-A, -B, -Cw, -DR and -DQ antigens before making any kidney, kidney-pancreas, pancreas, or pancreas islet offers.

Committee members agreed that DNA testing is not universally available in the middle of the night, is very expensive and takes more time to complete. The Committee agreed that although most labs may perform the test, they may not have the availability of performing the test on a 24 hour, 7-day a week basis. It would require more personnel and prolong the donor testing time from 50% – 100%. The Committee questioned whether or not this was a business driven proposal as opposed to a patient driven proposal. Although the Histocompatibility Committee states that all but 2 laboratories have the capability to perform this testing, the OPO Committee is concerned as many of the labs that members use do not have the capability to perform the testing at all times.

Members also agreed that there is no clinical importance to having these results pre-transplant for the allocation of organs except for a 6-antigen match and that this testing should not be required in the middle of the night.

Motion: That the Committee not approve the proposal, that clinically relevant data must be made available and that a survey of laboratories be done to assess whether or not they can perform these tests 24 hours a day and 7 days a week. The survey should also include the time frames for availability of testing and the results being available as well as the cost of testing.

The Committee does not approve of this proposed change as stated above by a vote of 10-0-0.

8. Proposal for the Placement of Non-Directed Living Donor Kidneys: Affected Policy: 12.5.6 (Recipient Selection for Organs from Nondirected Living Donor Organs) (Living Donor Committee)

This proposal would establish procedures for the placement of non-directed living donor kidneys. Under the proposal, transplant centers would select the recipient of non-directed living donor kidneys based on a list generated by the OPTN computer system used to identify potential recipients for transplant. This list is referred to as a match run.

Currently, when organs go to a transplant center, the center takes control of that organ and as such, there is a disadvantage to the other local candidates. If a patient goes to a transplant center, the center allocates the organ. However, if a patient goes to an OPO, than the OPO should be able to allocate the organ. The Committee agreed that this needs to be a more in depth proposal and questioned how this proposal would fit in with paired donation.

The Committee agreed that, although this is an excellent first step, it is incomplete and needs more work. This proposal really does not change the way living donor organs are being placed.

Motion: Support the proposal under the condition that if the OPO is involved in live kidney allocation, then the organ should be allocated from the entire list.

The motion was approved by a vote of 7-0-1

9. Proposal to Require Reporting of Non-utilized and Redirected Living Donor Organs - New Proposed Policy: Submission of Non-utilized Living Donor Organs (Policy 12.8.5) and Submission of Redirected Living Donor Organs (Policy 12.8.6) (Living Donor Committee)

These proposals require that the organ recovery center report all instances of:

- living donor organs recovered but not utilized for transplant
- living donor organs recovered but then redirected and transplanted into a recipient other than the intended recipient

These events would be reported through the UNet^{SM} Patient Safety System. If a living donor organ is transplanted into a recipient other than the intended recipient, all required donor and recipient information must still be submitted through Teidi.

Some OPOs are involved in live donation and this change appears to be a logical requirement. If the transplant center sends the organ to another center, then the OPO does not need to be involved.

The Committee supported this proposed policy change with a vote of 8-0-0.

11. Zip Codes for Imminent or Eligible Death Data Collection. Variations in Imminent and Eligible (I & E) data have been identified and it might be helpful to look at I & E data, not only by DSA, but by other geographic criteria, such as the home zip code. This may provide valuable demographic information. Currently, the zip code is collected, but not required on the DDR. For the data to be useful, it would need to be a required element. When the DDR was being created, the Committee made it optional because of the difficulty in getting the zip code for the I & E deaths that do not become donors. The zip codes would allow for data analysis that would look more deeply into the socio-economic data of populations to better predict the expected vs. actual donation rates. It was suggested that we collect the donor hospital zip code, however, that may not give a good indication of donor demographics.

It was determined that it is impossible to get these zip code data on every donor; however, it can be reported for eligible deaths. The Committee decided to table the discussion, conduct some research and review old cases, and discuss at a future time. It would also be helpful to analyze other pieces of information that are collected that would further explain the demographics of each OPO's I & E population.

12. Follow-up to Discussion Regarding the Maryland Aggregate Pathology Index (MAPI) Elements. Mr. Orlowski reported that the Organ Availability Committee (OAC) suggested that the MAPI scoring system be added to the data collection process when a biopsy is performed. The MAPI elements were published in the *American Journal of Transplantation* in 2008. Conclusions included that the elements demonstrate the value of histological evaluation of kidneys before implantation. MAPI is based on five histological characteristics of the pre-transplant wedge biopsy and stratifies the organs into low, intermediate and high risk of graft failure. This scoring system has the potential to help transplant physicians estimate outcome from the pre-implantation biopsy findings.

This project had been suggested several years ago and the data were inadvertently folded into the current OMB data collection project and placed on the mandatory deceased donor record form. Since this proposal did not follow the OPTN policy development process, the Committee opposed the change due to the potential data burden for the OPOs. It was suggested that these proposed changes follow the normal policy making process and vetted through all of the appropriate committees.

13. Documentation of Donor Weight in DonorNet®. The Committee considered a request from a member regarding the need to include documentation of donor weight in DonorNet®. Currently, the

weight is recorded at the time that the patient becomes a donor. These weights may vary dramatically from the "dry" weight" due to fluid resuscitation during donor management.

Members remarked that the admission weights may not be available or accurate due to the patient having a cast and other procedures. Some members felt that it was an admission weight or pre-admission weight that should be recorded vs. a weight taken at the time when the OPO is managing the donor. Members agreed that it would be impossible to get accurate weights to consider (e.g. children who are weighed prior to hospitalization).

The allocation weight should be that weight listed when the OPO secures the weight. This issue may not be as important on a large man, however, on children, weights can be essential in the allocation process. The question was asked as to whether or not this data field should be mandatory. It would be easier to determine the admission weight and it was suggested that this weight be the weight reported.

There are various reasons why weights vary and why reporting of these weights will need some explanation. The Committee agreed that communication needs to occur with all parties concerned to discuss whether or not the reported weight is the dry weight, admission weight or allocation weight. It is important for the clinical coordinator to clarify weights with the OPO coordinator. In practicality, there is only one weight field. However, having more is of no value as it will need clarification.

Some members opined that the OPO bears some responsibility when they are dealing with a weight sensitive recipient. Currently transplant centers are not aware of which weight they are receiving. From a data perspective, it would be helpful to know which weight is being provided. If not a data burden, it would be beneficial to have both if both data elements are valuable in assessing the donor and candidate. There is a place in DonorNet℠ to place notes regarding the data and it is recommended that OPOs provide information in the notes.

The Committee agreed that a memo should be sent stating that OPOs and centers should be guided that for allocation purposes the weight that is utilized is the admission weight or dry weight whenever possible. If that is not available then a measured weight should be utilized and clarified when the weight was taken and under what conditions.

1. In any circumstance when there is an admission weight available, that weight should be used in the allocation of organs
2. When not available, a note in DonorNet® should clearly indicate that the weight listed is not the allocation weight but a weight taken during donor management and or fluid resuscitation
3. In all circumstances, clinical practitioners on the recipient side should identify if weight is a critical issue they should discuss this information with the OPO Coordinator
4. If the Committee was to recommend a programming change to collect and admission weight and a weight at the time of consent, the programming issue would have to go through the OPTN process

The Committee agreed that this issue is an educational and communication issue and should not necessarily be a programming issue.

14. Molecular Typing for Deceased Donors. The Committee was asked by the Histocompatibility Committee to comment on a proposal to require molecular typing for deceased donors. This concept will identify unacceptable antigens and clearly doing virtual crossmatches that are predictive of good outcomes. There are only 7 or 8 labs that provide this testing 24/7. Many other labs would struggle to do these tests. Concerns were raised that included:

1. This change will extend the time for a complete donor evaluation from 6 hours to approximately 18-20 hours
2. This testing will increase costs as it requires more expensive equipment, additional staffing, and is not particularly feasible to use on all donors
3. Most of the information gained will be C-locus data and not of proven use for renal transplant outcomes

This testing is most relative when a 6 antigen match is involved. One member remarked that although the information would be interesting scientifically, it is not important clinically.

The Committee concluded that the C-locus data was not that valuable. After discussion, the Committee agreed that a memo should be drafted to the Histocompatibility Committee that will include the following:

1. This testing will extend time for the donor workup from 6 to 20 hours
2. This testing is very expensive; and
3. Information gained will not be of particular importance of proven use for renal outcomes

Motion: That the Committee support the proposed change.

The Committee did not support the proposed change with a vote of 0-15-0.

Subsequently, a memo was drafted and sent to the Histocompatibility Committee.

15. Returning Organs to an OPO. The MPSC requested that the OPO Committee evaluate the need for a requirement for OPO and Transplant Center to communicate when organs are returned to an OPO. This proposed change arises from a situation that occurred whereby the organ was sent to a transplant center and returned to the OPO. The OPO was not made aware that the organ had been partially anastamosed into a patient. The obvious implications of disease transmission, contamination, organ damage, etc. are apparent.

The Committee agreed that there needs to be verbal and written communication. Given time constraints that occur, the organ would not have been reallocated if the OPO would have been made aware of the situation. As part of policy, it might be prudent to include language that if a transplant center notifies an OPO that they will not use an organ and that it should be reallocated, it is incumbent upon the center to notify the OPO if the original packaging has been opened, if the organ has been removed from its original sterile packaging, if it has been placed on a field in the operating room, and/or if there has been any surgical intervention. The proposed language change is set forth below:

5.0 STANDARDIZED PACKAGING, LABELING AND TRANSPORTING OF ORGANS, VESSELS, AND TISSUE TYPING MATERIALS

The purpose of Policy 5.0 and its subsections is to:

- state requirements for packaging and labeling organs, tissue typing specimens, and vessels to prevent wastage (and/or to promote safe and efficient use)
- define terms and responsibilities related to packaging, labeling, and transporting organs, tissue typing specimens, and vessels; and
- state requirements for recovering, storing, and using vessels in solid organ recipients

The responsibility for packaging and labeling deceased donor organs is assigned to the Host OPO. Transplant Center staff may not leave the operating room without allowing the OPO to package and label the organ in accordance with OPTN Policy. The OPO must submit a report through the Patient Safety System when a Transplant Center fails to comply with this policy. The OPO will make all reasonable efforts to package and label the organ in a timely fashion. If an organ is repackaged by a transplant center for transport, the Transplant Center will package, label and ship the organ in accordance with this policy and immediately notify the recovering OPO of the repackaging.

Motion: That the proposed change be distributed for public comment.

The Committee approved of the proposed policy change by a vote of 15-0-0.

16. Work Group for Standardizing Abbreviations in DonorNet®. The Transplant Administrators Committee (TAC) is seeking input regarding their work with standardizing abbreviations in DonorNet℠. The Work Group is interested in developing a glossary of accepted terms and abbreviations and in evaluating opportunities to develop additional educational tools.

The TAC also suggested that the TAC DonorNet® Work Group merge with the recently formed "When Donor Information Changes" (WDIC) Work Group in order to eliminate duplicating efforts. The Committee agreed that the groups should be joined and that the TAC should continue with their efforts in standardizing abbreviations. The OPO Committee will provide a member to the Work Group. The TAC could also report their work at the WDIC Work Group meetings/calls to ensure that there is no duplication of effort.

At the April 20, 2010, meeting, Lynn Williams, Chair of the Abbreviations Subcommittee, provided an update on the subcommittee that is reviewing abbreviations for DonorNet®. The Subcommittee agreed that the list of suggested abbreviations is too long and decided to evaluate each item on the list and score each of the items as universally understood, somewhat understood, or should be removed. The subcommittee will arrive at a recommendation for the TAC. There has been mention that no abbreviations or a short list of accepted abbreviations be accepted. Members were asked to volunteer for serving on this subcommittee.

Members agreed that DonorNet® does not provide for a good method to exchange all information that changes and that verbal communication is essential.

17. Islet Cell Transplant. The Pancreas Committee is concerned that they do not see more pancreata offered for islet cell transplant and questioned whether or not it is because OPOs are unable to meet or are misinterpreting the regulations put forth by the FDA in 21-CFR-1271. After discussion, the Committee arrived at the following conclusions:

1) Logistics – Logistics is not just an issue of access to a lab/program performing islet transplants (although this is part of it due to time constraint and transportation issues). Logistics is also an issue in that the pancreas is often placed for whole-organ transplant and then, upon visualization or perfusion is deemed not usable as a whole organ; the OPO personnel then hurry to place the organ for islets and some/many islet centers are not able to respond quickly to these offers. Additionally, because the donor was taken to the OR with a whole organ transplant planned, it may be in the middle of the night and flights/transportation may not be available to get the organ to a lab in the required timeframe. For instance, getting a pancreas from Albany, NY to Chicago is not just a function of a 2 hour plane ride, but also the time of day and whether there are any available flights at all

2) Volume – Many labs can only receive and process one pancreas at a time which may result in the decline of good organs
3) Preservation solution – Some OPOs report that individual labs are only willing to accept UW or SPS while others will only accept HTK. Given that the preservation solution used by the OPO is usually driven by local whole organ programs (liver, pancreas, and kidney), flexibility on the part of the islet program in this matter would be helpful
4) Reimbursement – OPOs incur costs of evaluation, surgical recovery, preservation, and packaging/shipping whether the pancreas is ultimately used or not. However, with islets, the OPO is usually reimbursed only if the islets are used. If the reimbursement is at a reduced rate (as most islet centers request), there is a gap. What was clear from the Committee's discussion is the 21 CFR 1271 regulations are not a factor other than the receiving center's limitations on time and/or storage solutions which may result from the design of the individual program's attempt to meet FDA regulations

A memo will be sent to the Pancreas Committee that describes the Committee's conclusions.

At the April 20, 2010, meeting, Meg Rogers provided a summary of the Pancreas Committee's Islet Subcommittee work. This group was formed due to questions that were posed regarding the number of pancreata that are recovered and not transplanted, provisionally accepted and not transplanted. The issues that are being addressed include:

- the volume of islet centers accepting offers can only accept one offer at a time
- some centers do not accept the preservation solution that the OPO uses
- reimbursement issues

The Pancreas Transplantation Committee Chair requests that the OPO Committee provide members to the subcommittee. One member suggested that the list of islet cell centers funded by the NIH should be circulated as they are the centers most likely to accept pancreata.

18. Data Coordinator. The Committee was asked by the MPSC to provide input on whether or not a definition of data coordinator should be included in the bylaws and if so, provide a recommendation regarding the roles and responsibilities. Because of the importance of completeness, timeliness and accuracy of the data, the MPSC asked if this position should be placed in the bylaws and clearly defined. Currently, the clinical coordinator and the financial coordinator are listed as mandatory and defined in policy which serves as a precedent for this initiative. The Data Coordinator subcommittee has met by conference call and outlined what the roles are. The following proposed language was suggested.

The subcommittee agreed that this is an important position and, as such, these individuals would need to have competency training. Although data entry may be conducted by one individual, many individuals actually collect the data. It is the primary data coordinator who would be responsible for the data collection and the primary point of contact.

- In response to the MPSC questioning, should this position be defined in the bylaws?
  - Currently, every transplant center must designate a data coordinator in their center profile but there are no guidelines regarding the roles or responsibilities. As a practical matter, when the OPTN investigates data irregularities, they find that the person designated to be the data coordinator, may not be aware they are responsible and has never been trained. As such, should the OPTN provide guidance? The staff person entering the data does not need to know what the data mean. However, the Committee agreed that a knowledgeable person would need to oversee the data input and be held accountable for correcting any data

problems. The actual process should not be prescriptive but be left up to that OPO to develop. The data coordinator should be the primary point of contact
- OPO Data Coordinators may be clerical and not the contact person who would address issues. Need to clarify the individual responsibilities
- The format for the proposed language was derived from the financial coordinator language
- To have a primary coordinator will add credibility and accountability to the OPO and consistency to the process. One member commented the primary data contact may not be a coordinator but may be the Director of Quality. This title of Primary Data Coordinator may not be an accurate description of the responsibilities and may be better described as a clinical data contact or manager. The Committee also discussed the need for competency to be demonstrated. As such, there will be a need to identify thresholds for competency at which point sanctions may be posed

- The Committee agreed that the bylaws should have an overarching statement in the requirement for membership that the data submitted must be complete, accurate and timely and able to be validated

Mr. Orlowski asked the Committee to demonstrate informally how many agree with the concept of defining the position in the bylaws? The Committee unanimously agreed to the concept by a vote of 14-0-0.

- To what extent do you define the position?
  - The Subcommittee has developed a list of roles and responsibilities and agreed that the term "clinical" should not be in the OPO Data Coordinator description as it reflects the transplant coordinator
  - **Primary Data Officer/Controller.** It is the responsibility of the leadership of each OPO to ensure that all data reported to the OPTN are complete, accurate, and timely. To help ensure that this reporting occurs, all OPOs must identify one individual to serve as the Primary OPO Data Officer. This individual should have a thorough understanding of the entire donation process from donor identification and classification, and the procurement process through the allocation of organs and will serve as the primary data contact person at the OPO for the OPTN. As the Primary OPO Data Officer, this individual will work with the other OPO personnel to ensure that all required data are complete and accurate and are reported to the OPTN within the timeframes set in OPTN policy. The Primary OPO Data Officer is required to complete annual training and competency assessment provided by the OPTN

- Specific responsibilities should include, but are not limited, to:
  - Organize and maintain a process to facilitate the complete, accurate, and timely reporting of all data to the OPTN. Involvement in quality assurance reviews of all data reported
  - Maintain currency with OPTN Policies and Bylaws
  - Serves as a liaison to the OPTN for all data related issues; and
  - Maintain the confidentiality of all data

- If placed in the bylaws, should there be routine training opportunities?
  - Realistically, data officers need to be trained and we would ask UNOS to provide competency training, possibly web based, so the OPTN could rely on the data to be accurate
  - Data problems exist and some executive oversight is needed
  - Committee agreed that the training is an excellent opportunity for OPOs

In the memo to the MPSC, the following points will be stressed:

1. The definition of the position is the primary point of contact not the person who does the data entry
2. The person needs to have clear direction of the leadership for the organization to submit complete and accurate data
3. It is the expectation of the OPO Committee that the OPTN will provide periodic/annual training and competency assessment for those individuals in these positions so that they are up to date on terminology, forms, etc

Motion: That this basic outline describing the roles and responsibilities of the OPO Data Officer be submitted to the MPSC and that the MPSC consider the need for annual training and thresholds for competencies.

The motion was approved by a vote of 15-0-0.

19. When Donor Information Changes after the Offer is made. A new Joint Work Group has been formed to discuss the issues surrounding when donor information changes occur following an offer in DonorNet®. Given the technological costs for changes to DonorNet℠, the solutions may need to be educational in nature. The Work Group comprises representatives of the organ specific committees, Transplant Administrators (TAC), Transplant Coordinators and Pediatric Committees. The first conference call will be held on December 2, 2009. The Committee had a brief discussion regarding the breakdown in communication when donor information changes.

The Work Group met by conference call on February 3, 2010. DonorNet® provides a method for providing and accessing new information, but does not provide any type of notification that new information has been entered. Users are becoming accustomed to not talking and just using the electronic transfer of information. The group agreed that phone communication is still essential in the organ offer process and that good solid verbal communication should be the #1 guideline. Nothing can take the place of direct communication. Additionally, DonorNet® allows for offers on a wider geographic scale beyond the local area, so people do not always know to whom they are talking.

OPOs update values in DonorNet®; however, information in DonorNet® does not necessarily reflect the current status of the donor as it changes during donor management. One member described his OPO's process whereby prior to the match run; an administrator reviews all of the data. The group agreed that there is a need for basic standards for review and a determination as to what needs to be updated and how often.

It was determined that the Work Group should recommend standards or minimal guideline relative to the actual process as to how information is entered. These standards should include:

- The need to be timely as there for current information
- QA steps that need to be taken before data is entered
- Common sense guidelines for both OPOs and transplant centers to know what DonorNet® does, what it does not do, and what they need to do to get the best out of DonorNet®

Members agreed that there are many misconceptions in the field. People are currently relying solely on DonorNet® for information. Education is needed for OPOs and transplant centers and information could also be added to DonorNet® Help Documentation.

It was determined that the Work Group will review a list of fields that are currently required for an offer to be made. They will:

- Develop standards for minimum information entered (but standards that qualify)
- Develop best practices
- Develop an education plan for Live Meetings
- Will recommend an annual program to provide information to DonorNet® users about critical issues; and
- Compile list of items that need to be included in DonorNet® education

The Work Group agreed that multiple steps are needed that include:

- Mandatory online training
- A presentation at NATCO Annual Meeting targeting new users
- Users need to demonstrate competency through testing before they gain access (TAC looking at competencies)
- It may be necessary and possible to partner with other organizations; and
- Ongoing training for new users

At the April 20, 2010, meeting, Mr. Orlowski provided a summary of activities. The group has discussed the need to establish some language to go into policy that when a center has put in a provisional yes to an organ offer, the center should check DonorNet at intervals to assess changes, and that the OPO should reach out to the centers to let them know there is significant change in donor status. The Committee suggests that verbal communication is essential and policy language change is not necessary.

One member opined that it is the center that should take the responsibility to keep updated on donor changes. The group agreed that this is an educational opportunity and questioned as to who crafts educational opportunities in DonorNet® and who monitors it. It would, however, help to develop a short list of items that would trigger a phone call to the center. Some members did not feel there should be policy created as this is a communication issue.

The group opined that OPOs should not be making decisions as to what information is important as they do not make medical decisions. As the TAC may proceed with policy development, the Committee recommended that we have a conference call with TAC and have a short pre-call with our members. This could generate more calls in the middle of the night. When a center accepts a provisional "yes" the organ is going to be offered at some point by telephone when all the information is available.

Members were not sure what type of information would be expected to be relayed and agreed that all information that changes would be a burden. It is the center's responsibility to make sure the organ is safe prior to accepting the organ. There is some opportunity to improve the communication. One member posed a situation when several centers turn down an organ and another center requests a cardiac catheter. The Committee questioned whether or not it would be necessary to send the new information to all of the centers that turned the organ down.

The Committee will request that the TAC have a conference call with the Committee and prior to that call, the Committee will meet. The Committee should identify who has oversight of DonorNet® and identify key areas for automated alerts.

20. <u>Pancreas Committee – Concept for a National Allocation System</u>. At the November, 2009, meeting, Meg Rogers provided a presentation regarding the Concept of a Pancreas National Allocation System. The Pancreas Committee is evaluating how the pancreas might be allocated under the new

kidney allocation schema. The Pancreas Committee wants to move forward with the option of the combined list and would like feedback from the Committee.

The number of pancreas transplants has decreased in the last few years. Simultaneous kidney-pancreas transplants are performed second to kidney alone transplant. Graft function shows that simultaneous pancreas kidney has the highest graft survival rate with the pancreas alone having the lowest. Current allocation policy is not uniform nationally; many OPOs have the kidney follow the pancreas and others have the pancreas follow the kidney. The goal of this initiative is to have a uniform system of allocation.

There are some geographic inconsistencies for those waiting for combined kidney-pancreas transplants. The goal of the project is to ensure that no one group is disadvantaged. They wish to increase utilization, reduce waiting time without adversely affecting the adult and pediatric kidney transplant patients and reducing the geographic inequities.

After reviewing the data, the Committee discussed the proposed change (the kidney following the pancreas and that the pancreas is allocated with the combined SPK list and the pancreas list). There is also a development of consistent, simultaneous minimal listing criteria. Kidney follows pancreas means that the pancreas is allocated and the kidney is allocated with it ahead of the kidney list. This is different then the concept of the pancreas follows kidney where the kidney is allocated and if the patient needs a pancreas, the pancreas goes with the kidney. If not needed with a kidney, it is allocated individually.

The Committee discussed the proposed options for the allocation system and made the following comments. They agreed that if there is not a pancreas driven system, they have a difficult time allocating the pancreas alone.

It was noted that the number of pancreata will not change but it is the kidney that is transplanted with the pancreas that will be clarified.

- A combined list may be the most equitable as it does not disadvantage a particular group. The Committee understands that there are some medical arguments for transplanting a candidate who is on dialysis and who needs a pancreas, that there is a significant difference in survival on dialysis
- OPOs need guidance regarding which list to use, the pancreas list locally, particularly in the pediatric kidney alone list, vs. going to the SPK list
- SPK will precede paybacks
- Concerns were voiced regarding the allocation of KP as the priority following the pancreas. A diabetic who lists for a kidney alone, will wait ¼ time longer than the patient who is listed for a KP. Every good kidney goes to a pediatric patient or a KP. Allocation has never made an exception based purely on a disease. As in this case, a patient having a specific disease (diabetes) will have priority over every other patient with other diseases. They will be allocated in ¼ of the time of anyone else on the list that has a different disease
- The data show that the Ks follow the Ps in most cases except for approximately 4 centers where the P follows the K. These centers do very few transplants. The Committee noted that all of the data are being compared to a system where pancreata are already being allocated so kidneys are going with them and this is not a fair comparison. The comparison should be to what would happen when the P follows K as opposed to what is currently happening with the K following P. The Committee questioned whether or not the analysis looked at a combined SPK pancreas list and what the impact was on the ratio of waiting time between the pancreas kidney patient and the kidney alone patient. They felt it is an important variable to consider. With Model 9, pancreas

alone SPK combined list, the Committee questioned the impact for those who are waiting for a kidney alone and remarked that the number of kidneys available will most likely increase. These kidneys would most likely be very healthy and will have a high utilization rate. Currently, in one OPO candidates are getting bypassed on the kidney list because they are given SPK priority. Diabetic kidney pancreas candidates died faster on the waiting list than the kidney alone candidates, but lived longer with the transplant. The Committee would be interested to hear the Ethics Committee's consideration

- The Committee suggests a model simulation showing the impact for those patients who are waiting for a kidney alone

The OPO Committee is pleased that guidance will be provided to OPOs as to the allocation of these organs.

21. Donor Blood Cultures. The MPSC has requested that the Committee evaluate whether to develop a standard policy, requirements or guidance document for a specific time period when looking for previous positive cultures for donors that had been admitted to the hospital prior to donation. In other words, do we think there should be guidance/policy mandating a timeframe under which culture results need to be collected?

Recently a disease transmission occurred when a donor had negative results on blood cultures that were drawn at the time when the OPO began donor management. The OPO did not go back and get culture and sensitivity results on the blood cultures that had been drawn prior to taking over the care of the donor. The recipient contracted the same infection that appeared in the cultures prior to the brain death. This should serve as a clear reminder that OPOs must review all culture results on donors and not just the ones that the OPO orders. This information would be of great interest to the transplant center accepting the organ. The Committee considered the question, "Should there be a policy that requires all blood cultures from hospital admission be reviewed and shared?"

Although the Committee would welcome guidance on this subject and agreed that the information about any cultures within the same hospital visit might be exchanged. The question might be asked, "Has this patient had any positive cultures during this hospitalization?" All cultures, H1N1 testing, and TB or pending TB tests should be included. The members agreed that the wording might include all "infectious disease testing" instead of "cultures." A discussion surrounding the term "all" ended in agreement that the term should not be included. Additionally the Committee considered whether a timeframe for when results should be reported. Some patients are hospitalized for long periods of time and cultures might be months old and no longer relevant. Members expressed a need for guidance on this issue regarding the timeframe needed for reporting results

Motion: That a memo be sent to the DTAC stating that a policy statement and/or guidance document would be warranted and the OPO Committee would welcome the opportunity to participate with the DTAC in its development. It would be important to balance the infectious disease with the practical realities of being an OPO. This is also an opportunity to work with transplant centers to resolve conflicts that arise over this issue.

The Committee unanimously approved the concept by a vote of 13-0-0.

22. When is a Donor Counted, at Cross Clamp or upon OR entry? The Committee discussed differences between OPOs regarding when they consider that a donation has occurred or when the donor is counted. Members discussed the various ways that this time can be recorded: at cross clamp or when

the patient goes to the OR. Some members report it in multiple ways. Historically, the OPTN counts donors on the date that the donor goes to the OR. Most OPOs list the donor date as that of the cross clamp. When reports are run, the OPTN/SR may see a different number reported. Additionally, if the patient goes to the OR on a Friday night at 11:45 pm, the donor feedback form will not be completed until the following week and that would result in limited time to complete the form within the constraints of policy. The practicality is that it cannot simply be changed because in DonorNet^{SM} there are numerous places that look at when the patient went into the OR.

The Committee will revisit this topic and determine a path forward for this issue and include:

- Possible need for training so people are aware of problem
- A plan to correct problem

Eventually the entire data system will be rewritten and when that occurs, the Committee would like to make sure it is not reprogrammed in the same fashion. The cross clamp time is a very clear time to use; however, currently, "recovery date: Donor to the OR" appears frequently in the coding. There should be no difference in calculating these data and cross clamp time is a clearly defined time. This is also an important issue as the determination of Imminent and Eligible death data is influenced by the date. Members agree that the time should be listed for the DCD donor as the time of perfusion.

Members agree that it would be important to have a standard time that everyone (OPTN, SRTR, etc.) would use the same time to enhance consistency in the definition to result in more accurate data collection. A time of incision might also be used to provide consistency. Members were asked to identify any particular issue and provide feedback. Mr. Orlowski will draft a letter to the OPTN leadership to demonstrate the Committee's concern becoming more consistent going forward and recognize that it is a programming issue and not solved in the short term. These issues need to be addressed in the policy rewrite process. Additionally, there should be communication with and education for OPTN members so everyone can begin to interpret the data appropriately.

23. Commercial Airline Transport. The Committee discussed a recent situation that occurred when sending a kidney via a commercial airline and the pilot refused to accept the organ on the plane. Subsequently, they found that the airline policy allowed the pilot to determine if an organ could be placed on their flight. The OPO contacted their courier and the Organ Center and discovered that the issue does happen periodically. This practice affects organs and blood and can result in the wasting of organs.

UNOS staff reported on the development of an internal work group that is addressing the issue. Many OPOs report these occurrences but comment that it only happens several times a year. However, if the number of these instances is extrapolated to all OPOs, there is a significant number of organs being wasted. The only data currently available is from the Organ Center and these data are incomplete.

Members discussed several situations that have occurred and suggested one part of the solution might be to track the organs. With the new labels being pilot tested it might be prudent to contact the OC and Sterling to tell them about the new labels.

Members agreed that when this situation happens, it would important to make sure that the family is aware of the outcome. At this time, it is unclear as to how frequently this happens and how this might affect Patient Safety. It is important to quantify these events. The Committee is concerned about these events and the loss of organs and asked if the patient safety system be expanded to track incidents of logistical issues beyond individual control. Additionally, any data available should be reviewed.

At the April 20, 2010, meeting, UNOS staff reported that an internal UNOS group has reviewed the available data and looked at potential ways to remedy the problem of airline delays or refusal to accept organs on board planes. It was determined that each airline has different policies regarding the transport of organs. UNOS attempted to secure an aviation consultant but was unable to do so due to financial constraints. At this time, the OPTN leadership has moved the issue into the Living Donor Committee to review transport issues of living donors.

It was suggested that there may be a need for educational efforts to identify successful strategies in dealing with transportation issues and that the OPTN should communicate with the FAA. Members discussed that AOPO has offered several educational efforts regarding the problem and the University of Michigan had an educational offering regarding the implications. AOPO has data and does track the number of charter hours and total cost by OPO. It was suggested that education be offered to various pilot groups and the Committee would like to identify a congressman or senator who has oversight over the FAA.

The Committee agreed that this is a patient safety traceable item and that OPOs and transplant centers should report airline mishaps and organ wastage to the patient safety issue as a sentinel event.

24. Waivers for Kidney Offers. The Kidney Transplantation Committee requested that the Committee consider a situation whereby a center was offered a kidney on waivers, accepted it, and subsequently had the offer withdrawn by the OPO. The kidney was subsequently placed further down the list on waivers. The question was posed as to whether or not there should be some type of guidance that if waivers are offered, they should be offered uniformly. The member originally making the request felt the decision was based on an arbitrary assessment that the original transplant center that accepted the offer discards kidneys at a higher rate than other centers. The member also believed that there should be consideration of OPTN policy that would require that organ offers be made with consistent terms for their acceptance (full waivers, anatomic waivers, etc.) for all centers, not those designated by the sending OPO.

Members recognized that frequently they do not want to offer waivers when they begin to make offers, but offer the waivers at a later time as they move down their list and find the organ more difficult to place. The above mentioned case demonstrates that uniformity in offers becomes an issue. Once the offer is made on waivers and accepted, they should not withdraw it but initially it can be done without waivers.

The Committee was asked to consider whether there should be some type of guidance that waivers should be offered uniformly. The Committee discussed the issue and determined that waivers do not appear in OPTN policy as it is an OPO specific determination to offer any waivers with an organ offer. The Committee did agree that once an offer is made and accepted, unless there is a logistical reason why the organ cannot be used, the offer should not be withdrawn.

1. This issue is about good business practice and should not be legislated in OPTN policy. If an offer is changed, there is a verbal agreement. It would be impossible to mandate good business practice when it is not a policy.
2. OPTN policy already indicates that when an offer is made and accepted, that offer should be honored unless there is a logistical problem causing the organ to be wasted.

A memo will be sent to the Kidney Transplantation Committee with the Committee's response.

At the April 20, 2010, meeting, the Committee was asked to discuss the issue again with the additional information that the host OPO had specifically excluded a particular OPO when offering the waivers for an organ. The Committee agrees that OPOs should not be singled out and that waivers should be offered

consistently. As this is one incident, policy should not be created to solve one problem. The Committee agrees that this is a reimbursement issue and the OPTN should not get involved in reimbursement issues. The Committee did not agree with the practice of a host OPO singling out a particular OPO and stating that they will not offer the organ to that OPO. They agreed that it disadvantages those organizations and patients and is very bad business practice.

25. Standardizing ABO Verification at Donor Hospitals**.** An OPTN member has asked the Committee to consider whether or not it is possible to develop a standardized ABO Verification document for donor hospitals to use. After a brief discussion, the Committee agreed that there is no way that the OPTN can mandate a standard document for donor hospitals to report an ABO.

26. AHIRC Proposals**.** The Ad Hoc International Relations Committee has requested the Committee's input regarding several proposals that they are formulating. The original version had a great deal to do with OPOs exporting organs and transplant centers importing organs. The current version focuses on organs brought into the country from an outside source, which was the Committee's original response. These new changes apply more to transplant centers, it is unknown if an OPO is involved in helping to facilitate the transport from another country.

Motion: Due to time constraints, it was recommended that the Committee have a separate conference call to discuss this issue.

The motion was approved by a vote of 14-0-0.

27. Koldtogo Container**.** The Department of Evaluation and Quality is seeking the Committee's input regarding a particular container (Koldtogo) that is being used by an OPO and whether or not the container meets policy requirements for shipping organs. This container, a large square, foil Ziploc bag with insulation and an internal white plastic liner, is used inside of the shipping box. The Committee understands that the container meets the "R" factor policy requirement, although it is not 1 ½ inch foam. The Committee agrees that if it meets the "R" factor, then it meets policy requirements.

Motion: That the Committee communicate with the DEQ that the Koldtogo container is acceptable and in compliant with current policy as long as there is proper documentation that the insulating capacity or "R" factor is met.

The motion was approved by a vote of 13-0-1.

28. Adding Search Criteria to Teidi®. A request has been made to add search criteria to the OPO Report in Tiedi® and add Creatinine at one, two, or three years post-transplant. There is no data burden for the OPO however, the OPO would be able to see those data and they would provide the OPO with additional information.

Motion: That the search criteria be added to the OPO report in Tiedi®.

The motion was approved with a vote of 14-0-0.

29. Storage of Vessels. At this time, transplant centers do not universally report the disposition of the vessels and there is no verification that these vessels are maintained as sterile. Currently vessels are sent with the organ and if not used, they are stored to be used on another patient. There is policy that deals with potential disease transmission and patient safety as a result of the rabies case.

There is no audit mechanism requiring that these vessels be stored properly, tested for sterility, and maintained under sterile conditions. Newly proposed language states that there be 3 sterile barriers if vessels are not packaged with the organ with the outermost container labeled with the infectious disease information. The Committee wants this practice reviewed because it does not believe that this practice sufficiently protects the recipient. This practice is not being controlled and it will ultimately become a tissue banking issue and the FDA will become involved. The group will discuss this on the conference call in May.

OPO Committee Meeting Attendance	Date	Jan 12	April 20	May 10
	FORMAT (select)	Live Meeting/ Tele-conf	In Person	Live Meeting/ Tele-conf
NAME	COMMITTEE POSITION			
Jeffrey Orlowski MS, CPTC	Chair	x	X	X
Lori Brigham MBA	Vice Chair	x	X	X
George Lipkowitz MD	Regional Rep.	x	X	
Michael Holman MD	Regional Rep.	x		X
Lynn Williams	Regional Rep.	x	X	X
Patrick Giordano CHE	Regional Rep.	x		X
Sean Van Slyck BA,CPTC	Regional Rep.	x		X
Craig Van De Walker LRCP, CPTC	Regional Rep.	x	X	
Meg Rogers	Regional Rep.	x	X	X
Suzanne Lane Conrad RN, MS	Regional Rep.		X	
Rob Kochik RN, BSN	Regional Rep.	x	X	X
Gordon Bowen MS	Regional Rep.	x		X
Michael Marvin MD	Regional Rep.	x	X	X
Jim Carter	At Large		X	
Danielle Cornell RN,BSN,CPTC	At Large		X	X
G. Kent Holloway MSF	At Large	x	X	X
Lori Markham RN, MSN, CCRN, CPTC	At Large	x	X	X
Richard Pietroski MS, CPTC	At Large	x	X	X
M. Kevin Stump BS, BSN, CPTC	At Large	x		
Mary Nachreiner	BOD		X	X
Charlie Alexander	BOD	x		X
Robert Walsh	HRSA			X
Teresa Beigay	HRSA		X	X
Emily Messersmith Ph.D.	SRTR Liaison	x	X	X
Robert Wolfe Ph.D.	SRTR Liaison	x	X	
Franki Chabalewski RN, MS	OPO Committee Liaison	x	X	X
John Rosendale	Support Staff	x	X	X
Margaret Kearns	DEQ			
Stacey Burson	Business Analyst	X	X	X
Shandie Covington	Liaison DTAC			X